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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,233	08/27/2003	Mark Gelfand	jhn-3659-72	3768

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
11/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,233	GELFAND ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33-41,50-53 and 55-59* is/are allowed.

6)☒ Claim(s) *32,42-49,54 and 60-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Examiner acknowledges Applicant's 6 September 2007 amendment. Claims 32-72 are currently pending.

By this amendment, applicant has added claimed 42-72 which correspond to originally presented claims 1-31, which were cancelled in the 27 August 2003 preliminary amendment.

In the Office action mailed 12 January 2007, Examiner mistakenly substantively examined claims 1-31, which had been cancelled by the Preliminary Amendment.

Upon becoming aware of the error, the Examiner withdrew the rejection of claims 1-31, and addressed properly pending claims 32-41 in an non-final action on the merits of the claims.

As applicant newly presents claims 42-72, this Office action addresses the invention of these claims as well as previously pending claims 32-41. Since this amendment changed the scope of the previously pending claims, and introduces claims that differ in scope from the originally examined claims, the following action is a FINAL action on the merits of claims 32-72, which was necessitated by Applicant's amendment.

Terminal Disclaimer

2. The terminal disclaimer filed on 11 April 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of

US 6,689,086 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

3. Claims 64-72 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant claims "a system as in claim 62," but claim 62 refers to a method. For the purposes of examination, Examiner assumes that claims 64-72 are intended to depend from apparatus claim 63.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 42, 48, 49, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,469,593 to Ishihara et al.

In the specification and figures, Ishihara discloses a method of using osmotic pressure measurements to control the rate of fluid withdrawal from a patient. Blood from a patient is fed via an arterial blood line 16 to a dialyzer 18 that, among other tasks,

removes water from the blood (see column 4, line 60 to column 5, line 45). Treated blood returns to the patient via line 20 and is pumped via pump 22. The dialyzer is supplied with dialysate solution via pump 28. In an embodiment, the apparatus measures electrical resistivity of blood and waste filtrate (that is, on both sides of the membrane in dialyzer 18) and uses that resistivity calculation to generate a measurement of osmotic pressure differential that is used to to control the rate of the filtrate pump (see column column 7, line 10 to column 8, line 22, column 9, lines 5-20). Accordingly, Ishihara discloses all the steps for the claimed method, and therefore necessarily performed the intended use of the method stated in the preamble, i.e. the use of transmembrane osmotic pressure measurements to prevent hypotension in a patient.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 32, 63-69, 71, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,202,764 to Afflerbaugh.

In the specification and figures, Afflerbaugh discloses the device as claimed by applicant. With regard to claims 32 and 63, Afflerbaugh discloses a device for controlling ultrafiltration comprising a blood withdrawal passage 12a that receives blood from a patient and an infusion blood passage 12b that returns treated blood to the

patient from filter 12 (see FIG 1, column 3, lines 1-8). The filter 12 comprises a filter or dialysis input 12c and output 12d. The device further comprises a pressure measurement device comprising a filtrate chamber in the form of outlet line 24, blood chamber in the form of blood inlet and outlet lines connected to inlet 12a and outlet 12b, and a semipermeable membrane in dialyzer 12 (see columns 2-3, FIG 1). The device further comprises blood-side pressure detectors 44, 46, and filtrate side pressure detectors 48, 50, which are capable of measuring a pressure differential between the filtrate side and the blood side of the device. A pressure controller 52 uses the pressure measurements to control at least filtrate pump 34 and pressure within the apparatus.

With regard to the recitation of measuring an osmotic pressure level and adjusting the rate of fluid flow based on the measured values, Applicant claims a controller that receives pressure measurements, determines an osmotic pressure from the measured values, and adjusts pumping rates based on the calculated pressure. Such a recitation is considered by the Examiner to be a recitation of the function of the claimed apparatus. It has been held that a recitation in which a claimed apparatus is intended to function fails to differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. It is the position of the Examiner that the Afflerbaugh controller is capable of employing an algorithm within the controller to use the pressure measurements to generate an osmotic pressure value as claimed by applicant. Accordingly, the Afflerbaugh apparatus is capable of performing as claimed by applicant and meets the limitations of the claim.

With regard to claim 64, Afflerbaugh discloses that the filtration device comprises a controller 52 that stores algorithms to control operation of the system based on predetermined and measured parameters (see column 5, lines 1-15).

With regard to claims 65 and 66, such a statement of the operation of the device is considered by the examiner to be a statement of the function of the claimed device. It has been held that recitations with respect to the manner in which a claimed apparatus is intended to be employed fail to differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the controller disclosed by Afflerbaugh is capable of being programmed to operate as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 67-69, Afflerbaugh discloses that dialyzer 12 filters blood and performs ultrafiltration, rendering it a hemofilter and dialyzer, as well as an ultrafilter (see column 2, lines 19-50).

With regard to claims 71 and 72, Afflerbaugh discloses pressure sensors 44, 46, 48, 50 located in the blood lines and the filtrate lines that together measure the difference between blood pressure and filtrate pressure during system operation (see column 5, lines 16-23).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 43-47 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,469,593 to Ishihara et al.

In the specification and figures, Ishihara discloses the method substantially as claimed by applicant with the exception of the use of particular values claimed by applicant to adjust the filtrate pump. With regard to claims 43-46, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In the instant case, Ishihara discloses the use of preprogrammed parameters to control the disclosed filtration process. Specifically, Ishihara takes electrical resistance measurements (which correlate with osmotic pressure) of the fluid on either side of the membrane and compares those measurements with predetermined values to control the filtrate pump to maintain the blood's parameters within a programmed range (see column 8, lines 1-22). It is the position of the Examiner that Ishihara suggests the use of various parameters (such as a maximum pressure difference, difference in pressure, operated-selected pressure) to keep the blood within the required range is not a patentable improvement over the method disclosed by Ishihara, and therefore, it would have been obvious to one having ordinary skill in the art to adjust the parameters disclosed by Isihara in order to keep the blood parameters within the desired range.

With regard to claim 47, Ishihara discloses that waste fluid is discharged to a waste circuit 82, which Examiner considers to be equivalent to applicant's claimed collection bag.

With regard to claims 60-62, Ishihara does not specifically disclose a duty cycle that regulates filtration rate. However, Ishihara specifically discloses that the filtration rate reduces by reducing the pressure applied by the ultrafiltrate pump. It is the position of the examiner that such a reduction may comprise a reduction to zero, suggesting that the ultrafiltrate pump 28 may be stopped to regulate fluid removal, thereby suggesting the method claimed by applicant.

10. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,202,764 to Afflerbaugh in view of US 4,469,593 to Ishihara et al.

In the specification and figures, Afflerbaugh discloses the apparatus substantially as claimed by applicant with the exception of an osmotic pressure sensor separated from the blood filter. Ishihara discloses a resistivity sensor 36b remote from filter 74 (see FIG 5) that measures a resistance that is extrapolated to osmotic pressure. The measurement is used to control fluid flow to prevent patient hypertension. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a sensor as disclosed by Ishihara to the system disclosed by Afflerbaugh in order to provide a measurement of osmotic pressure to control fluid flow, as taught by Ishihara.

Allowable Subject Matter

11. Claims 33-41, 50-53, and 55-58 are allowed.

12. The following is an examiner's statement of reasons for allowance: The prior art fails to disclose or suggest the method claimed by applicant.

Afflerbaugh teaches the method of setting a desired transmembrane pressure based on ultrafiltration rate, but does not teach or fairly suggest the use of an osmotic pressure measurement to control fluid flow through the system.

Ishihara discloses the use of an extrapolated osmotic fluid pressure measurement to control fluid flow and prevent hypotension, but does not disclose the steps of halting either filtrate flow or blood flow or both through a filtration system and using a pressure difference across a semipermeable membrane to measure osmotic pressure and using the osmotic pressure measurement to adjust the rate of fluid removal from the blood.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

13. Applicant's amendments and arguments filed 6 September 2007 have been entered and fully considered.

14. Applicant's arguments with regard to claim 32 are not persuasive. Applicant argues that Afflerbaugh does not comprise a separate osmotic pressure measurement device. However, applicant has not claimed such a device. Applicant has only claimed a controller capable of computing osmotic pressure based on pressure measurements

within the system. It is the position of the Examiner that the Afflerbaugh device is capable of performing the claimed function, meeting the limitations of the claims.

Conclusion

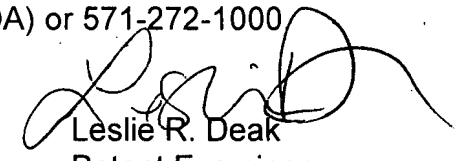
15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
30 October 2007